

UNITED STATES PATENT APPLICATION

OF

JAN OTTO SOLEM, PER OLA KIMBLAD, ERWIN BERGER AND
MICHAEL SCHWAGER

FOR

METHOD AND DEVICE FOR TREATMENT OF MITRAL
INSUFFICIENCY

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. patent application Ser. No. 09/345,475 that was filed on June 5 30, 1999.

BACKGROUND OF THE INVENTION

1. Technical Field of the Invention

The present invention generally relates to a device 10 and a method for treatment of mitral insufficiency and, more specifically, for treatment of dilatation of the mitral annulus.

2. Description of the Prior Art

Mitral insufficiency can result from several causes, 15 such as ischemic disease, degenerative disease of the mitral apparatus, rheumatic fever, endocarditis, congenital heart disease and cardiomyopathy. The four major structural components of the mitral valve are the annulus, the two leaflets, the chordae and the papillary 20 muscles. Any one or all of these in different combinations may be injured and create insufficiency. Annular dilatation is a major component in the pathology of mitral insufficiency regardless of cause. Moreover, many patients have a mitral insufficiency primarily or 25 only due to posterior annular dilatation, since the

3

annulus of the anterior leaflet does not dilatate because it is anchored to the fibrous skeleton of the base of the heart.

Studies of the natural history of mitral insufficiency have found that totally asymptomatic patients with severe mitral insufficiency usually progress to severe disability within five years. At present the treatment consists of either mitral valve replacements or repair, both methods requiring open heart surgery. Replacement can be performed with either mechanical or biological valves.

The mechanical valve carries the risk of thromboembolism and requires anticoagulation, with all its potential hazards, whereas biological prostheses suffer from limited durability. Another hazard with replacement is the risk of endocarditis. These risks and other valve related complications are greatly diminished with valve repair.

Mitral valve repair is theoretically possible if an essentially normal anterior leaflet is present. The basic four techniques of repair include the use of an annuloplasty ring, quadrangular segmental resection of diseased posterior leaflet, shortening of elongated chordae, and transposition of posterior leaflet chordae to the anterior leaflet.

Annuloplasty rings are needed to achieve a durable reduction of the annular dilatation. All the common rings are sutured along the posterior mitral leaflet adjacent to the mitral annulus in the left atrium. The Duran ring 5 encircles the valve completely, whereas the others are open towards the anterior leaflet. The ring can either be rigid, like the original Carpentier ring, or flexible but non-elastic, like the Duran ring or the Cosgrove-Edwards ring.

10 Effective treatment of mitral insufficiency currently requires open-heart surgery, by the use of total cardiopulmonary by-pass, aortic cross-clamping and cardioplegic cardiac arrest.

To certain groups of patient, this is particular 15 hazardous. Elderly patients, patients with a poor left ventricular function, renal disease, severe calcification of the aorta, previous cardiac surgery or other concomitant diseases, would in particular most likely benefit from a less invasive approach, even if repair is 20 not complete. The current trend towards less invasive coronary artery surgery, without cardiopulmonary by-pass, as well as PTCA will also call for a development of a less invasive method for repair of the often concomitant mitral insufficiency.

SUMMARY OF THE INVENTION

Therefore, a first object of the present invention is to provide a device and a method for treatment of mitral insufficiency without the need for cardiopulmonary bypass and without opening of the chest and heart.

5 A second object of the invention is to provide

reduction of the mitral annulus using only catheter based technology.

According to the present invention, a device for treatment of mitralis insufficiency comprises an elongate body having such dimensions as to be insertable into the coronary sinus and having two states, in a first state of which the elongate body has a shape that is adaptable to the shape of the coronary sinus, and to the second state of which the elongate body is transferable from the said first state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus is reduced as well as the circumference of the mitral valve annulus, when the elongate body is positioned in the coronary sinus. More precisely, the elongate body comprises a distal stent section, a proximal stent section and control wires for reducing the distance between the distal and proximal stent sections. Thus, means are provided for the transfer of the elongate body to the second state by shortening it from a

larger radius of curvature to a smaller radius of curvature.

The control wires may comprise a first wire and means for guiding said first wire in a course extending 5 two times between the distal and proximal stent sections, when the distance therebetween is at a maximum, and extending at least three times between the distal and proximal stent sections, when the distance therebetween is at a minimum.

10 To accomplish changes in the course, the guiding means preferably comprises a first eyelet fixed to one of the distal and proximal stent sections, a second eyelet fixed to the other of the distal and proximal stent sections, and a third eyelet positioned between the 15 distal and proximal stent sections, said first wire having a first end fixed to said one of the distal and proximal stent section and extending therefrom via the third eyelet, the first eyelet and the second eyelet back to the third eyelet where a second end of the first wire 20 is fixed. By this structure the maximum distance between the two stent sections will be about 1.5 times the minimum distance between the two stent sections.

A larger quotient may be obtained by extending the 25 first wire from the first eyelet at least once more via the third eyelet and the first eyelet before finally

extending the first wire via the second eyelet back to the third eyelet where the second end of the first wire is fixed.

In order to reduce the distance between the distal 5 stent section and the proximal stent section, said first eyelet is preferably fixed to the distal stent section and said control wires comprise a second wire extending through the third eyelet and as a double wire proximally therefrom out of the coronary sinus and out of the human 10 body. As an alternative to this second wire, a single wire may be used having an end releasably fixed to the third eyelet and extending as a single wire proximally therefrom out of the coronary sinus and out of the human body. However, to be able to also increase the distance 15 between the distal stent section and the proximal stent section, said control wires may comprise a third wire extending through the third eyelet and as a double wire distally to and through the first eyelet and then as a double wire proximally therefrom out of the coronary 20 sinus and out of the human body.

Alternatively, the distance between the distal stent section and the proximal stent section may be reduced by fixing the first eyelet to the proximal stent section. Then, said control wires should comprise a second wire 25 extending through the third eyelet and as a double wire

distally to and through the first eyelet and then as a double wire proximally therefrom out of the coronary sinus and out of the human body. In order to be able to increase the distance between the distal stent section and the proximal stent section in this case, the control wires should comprise a third wire extending through the third eyelet and as a double wire proximally therefrom out of the coronary sinus and out of the human body.

5 It should be noted that when the proximal and distal 10 stent sections have been fixed relative to the coronary sinus and the distance between them thererafter has been finally adjusted to a desired value, the second and the 15 third wires may in both the described alternatives be withdrawn from the coronary sinus by pulling one of their ends positioned outside of the coronary sinus and outside of the human body.

In preferred embodiments of the device, a cover encloses the wires in their courses between the distal and proximal stent sections so as to eliminate the risk 20 that the wires will injure the coronary sinus by cutting into its internal surfaces.

The cover may comprise one or more plastic sheaths and may also comprise one or more helical wires.

In an alternative embodiment, the device for 25 treatment of mitral annulus dilatation comprises an

elongate body having such dimensions as to be insertable into the coronary sinus and having two states, in a first of which the elongate body has a shape that is adaptable to the shape of the coronary sinus, and to the second of 5 which the elongate body is transferable from said first state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus is reduced as well as the circumference of the mitral valve annulus, when the elongate body is positioned in the coronary 10 sinus, said elongate body comprising at least one stent section at a distance from each end of the elongate body, said stent section providing a reduction of its length when expanded in situ in the coronary sinus, whereby the elongate body is shortened and bent to a smaller radius 15 of curvature.

Preferably, the elongate body of this embodiment comprises a proximal stent section, a distal stent section and a central stent section, the distal and proximal stent sections being expandable prior to the 20 central stent section. Obviously, this will result in a reduction of the distance between the proximal and distal stent sections. Further, the proximal and distal stent sections should be expandable without substantial length reduction.

Thus, the present invention takes advantage of the position of the coronary sinus being close to the mitral annulus. This makes repair possible by the use of current catheter-guided techniques.

5 The coronary veins drain blood from the myocardium to the right atrium. The smaller veins drain blood directly into the atrial cavity, and the larger veins accompany the major arteries and run into the coronary sinus which substantially encircles the mitral orifice 10 and annulus. It runs in the posterior atrioventricular groove, lying in the fatty tissue between the left atrial wall and the ventricular myocardium, before draining into the right atrium between the atrial septum and the post-Eustachian sinus.

15 In an adult, the course of the coronary sinus may approach within 5-15 mm of the medial attachment of the posterior leaflet of the mitral valve. Preliminary measurements performed at autopsies of adults of normal weight show similar results, with a distance of $5,3 \pm 0,6$ mm at the medial attachment and about 10 mm at the 20 lateral aspect of the posterior leaflet. The circumference of the coronary sinus was $18,3 \pm 2,9$ mm at its ostium (giving a sinus diameter of the septal aspect of the posterior leaflet of $5,8 \pm 0,9$ mm) and $9,7 \pm 0,6$

11

mm along the lateral aspect of the posterior leaflet
(corresponding to a sinus diameter of $3,1 \pm 0,2$ mm).

BRIEF DESCRIPTION OF THE DRAWINGS

5 The invention will be better understood by the
following description of preferred embodiments referring
to the appended drawings, in which

FIG. 1 is a cross-sectional view of a part of a
heart,

10 FIGS 2 and 3 are schematic views of a first
embodiment of a device according to the present
invention,

15 FIGS 4-6 are schematic views illustrating an
instrument, which may be used when positioning the device
shown in FIGS 2 and 3 in the coronary sinus,

FIG. 7 is a partial, enlarged view of the first
embodiment shown in FIG. 2.

20 FIGS 8 and 9 are schematic views illustrating the
positioning of the device of FIGS 2 and 3 in the coronary
sinus.

FIGS 10 and 11 are schematic views illustrating the
positioning of a second embodiment of the device
according to the present invention in the coronary sinus,

FIGS 12 and 13 are schematic views illustrating the positioning of a third embodiment of the device according to the present invention in the coronary sinus.

FIG 14 illustrates a fourth embodiment of the device according to the present invention.

FIG. 15 is a schematic view illustrating a preferred operation of the fourth embodiment.

FIG. 16 is a schematic view illustrating the operation of a fifth embodiment of the device according to the present invention.

FIG. 17 illustrates a sixth embodiment of the device according to the present invention.

FIG. 18 illustrates a further modification of the embodiments of FIGS 14-17.

FIGS 19 and 20 illustrate a seventh embodiment of the device according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG 1 is a cross-sectional view through the heart area of the posterior atrioventricular groove 1, which is filled with fatty tissue. It shows the posterior leaflet 2 of the mitral valve and the adjoining parts 3, 4 of the atrial myocardium and the ventricular myocardium. The coronary sinus 5 is shown close to the mitral annulus 6 and behind the attachment 7 of the posterior leaflet 2.

Since the coronary sinus 5 substantially encircles the mitral annulus 6, a reduction of the radius of curvature of the bent coronary sinus 5 also will result in a diameter and circumference reduction of the mitral 5 annulus 6.

The device of FIG. 2 comprises an elongate body 8 made of memory metal, e.g. Nitinol, or other similar material which has a memory of an original shape, illustrated in FIG. 3, and can be temporary forced into another shape, illustrated in FIG. 2. This elongate body 10 comprises one, two or more memory metal strings 9 of 8 helical or other shape so as to fit together and be able of permitting the movements described below. Along the elongate body 8 several hooks 10 are fastened so as to 15 extend radially out therefrom. These hooks 10 are covered by a cover sheath 11 in FIG. 2.

The elongate body 8 is forced into a stretched or extended state by means of a stabilizing instrument 12 shown in FIG. 4. This instrument 12 has two arms 13 at a 20 distal end 14 of a rod 15 and a locking means 16 at a proximal end of the rod 15. The distance between the ends of the rod 15 corresponds to the desired length of the elongate body 8 when being inserted into the coronary sinus 5.

The arms 13 are free to move between the position shown in FIG. 4 and a position in alignment with the rod 15, as shown in FIG. 6. The locking means 16 has two locking knobs 17, which are pressed radially outwards from the rod 15 by two spring blades 18. Thus, the elongated body 8 can be pushed over the rod 15 of the stabilizing instrument 12, then stretched between the arms 13 and the knobs 17, and finally locked in its stretched state on the stabilizing instrument 12 between the arms 13 and the knobs 17, as illustrated in FIG. 5.

The rod 15 may be a metal wire which is relatively stiff between the distal end 14 and the locking means 16 but still so bendable that it will follow the shape of the coronary sinus 5. Proximally of the locking means 16 the metal wire of the stabilizing instrument 11 is more pliable to be able to easily follow the bends of the veins.

The above-described elongate body 8 is positioned in the coronary sinus 5 in the following way:

An introduction sheath (not shown) of synthetic material may be used to get access to the venous system. Having reached access to the venous system, a long guiding wire (not shown) of metal is advanced through the introduction sheath and via the venous system to the coronary sinus 5. This guiding wire is provided with X-

ray distance markers so that the position of the guiding wire in the coronary sinus 5 may be monitored.

The elongate body 8 is locked onto the stabilizing instrument 12, as shown in FIG. 5, and introduced into the long cover sheath 11 of synthetic material. This aggregate is then pushed through the introduction sheath and the venous system to the coronary sinus 5 riding on the guiding wire. After exact positioning of the elongate body 8 in the coronary sinus 5, as illustrated in FIG. 8 where the mitral valve 19 is shown having a central gap 20, the cover sheath 11 is retracted exposing the elongate body 8 within the coronary sinus 5. This maneuver allows the hooks 10 on the elongate body 8 to dig into the walls of the coronary sinus 5 and into the heart. The elongate body 8 is still locked on to the stabilizing instrument 12 such that the hooks 10 engage the walls of the coronary sinus 5 in the stretched or extended state of the elongate body 8.

A catheter 21, shown in FIG. 6, is pushed forward on the guiding wire and the rod 15 for releasing the elongate body 8 from the locking means 16 by pressing the spring blades 18 towards the rod 15. This movement releases the knobs 17 as well as the arms 13 from engagement with the elongate body 8 which contracts as illustrated in FIG. 9, thereby shortening the radius of

curvature of the coronary sinus. As a result, the mitral valve annulus 6 shrinks moving the posterior part thereof forward (shown by arrows in FIG. 9). This movement reduces the circumference of the mitral valve annulus 6 and thereby closes the central gap 20.

5 FIG. 7 illustrates a part of an arrangement of the wires 9 and the hooks 10 along a peripheral part of the elongate body 8, whereby the elongate body 8 will be asymmetrically contracted resulting in a bending thereof 10 when interconnecting parts 22 of at least some of the hooks 10 are shortened to an original shape.

FIGS 10 and 11 illustrate an alternative embodiment of an elongate body 8', which is a solid wire in the shape of an open U-shaped ring that will engage the wall 15 of the coronary sinus 5 most adjacent to the mitral valve annulus 6 when inserted into the coronary sinus 5. The elongate body 8' consists of a memory metal material which when reverting to its original shape will bend as illustrated in FIG. 11. The return of the open ring 8' to 20 its original shape may be initiated in several ways, as is obvious to the man skilled in the art.

The third embodiment of the elongate body 8", illustrated in FIGS 12 and 13, comprises three stent sections 23-25 positioned at one end of the elongate body 25 8", at the middle thereof and at the other end of the

elongate body 8", respectively. These stent sections 23-
25 may be positioned in the coronary sinus 5 as
illustrated by conventional means, such that their
positions are fixed. They are connected by wires 26, 27,
5 which may be manœuvred from outside the vein system such
that the distances between the adjacent stent sections
23, 24 and 24, 25 are reduced. More specifically, these
distances are reduced asymmetrically, i.e. more on the
side of coronary sinus 5 most adjacent to the posterior
10 part of the mitral valve annulus 6. Thereby, the elongate
body 8" is bent, as illustrated in FIG. 13, and presses
the coronary sinus 5 against the mitral valve annulus 6
closing the gap 20.

A fourth embodiment of the device is shown in FIG.
15 14 as comprising two stent sections, more precisely a
proximal stent section 30 and a distal stent section 31.
The fourth embodiment further comprises a first eyelet
32, which is fixed to a preferably proximal part of the
31, which is fixed to the distal stent section 31, a second eyelet 33, which is
20 fixed to a preferably distal part of the proximal stent
section 30, and a third eyelet 34, which is positioned
between the proximal and distal stent sections 30, 31.
These sections 30, 31 are joined by a wire 35, one end of
which is fixed to the distal stent section 31. The
25 wire 35 may be fixed to the distal stent section 31 at a

proximal point, as shown in FIG. 14, or at a more distal point up to the distal end of the distal stent section

31.

From the distal stent section 31 the wire 35 extends 5 to and through the third eyelet 34 and then back towards the distal stent section 31 to and through the first eyelet 32. From the first eyelet 32 the wire 35 then extends to and through the second eyelet 33 and then finally to the third eyelet 34, the other end of the wire 10 35 being fixed to this third eyelet 34.

By moving the third eyelet 34 towards the proximal stent section 30, the distance between the proximal and

distal stent sections 30, 31 will be reduced. On the contrary, by moving the third eyelet 34 towards the 15 distal stent section 31, the distance between the proximal and distal stent sections may be increased.

However, such increase will require some means pushing the distal stent section 31 in a distal direction away from the proximal stent section 30 or pulling the 20 proximal stent section in a proximal direction away from the distal stent section 31.

The distance between the proximal and distal stent sections 30, 31 will reach a maximum when the third eyelet 34 is positioned close to the distal stent section

31 and will reach a minimum when the third eyelet 34 is positioned close to the proximal stent section 30.

The third eyelet 34 may be moved towards the proximal stent section 30 by means of a single wire 36, 5 which has an end releasably fixed to the third eyelet 34 and extends proximally therefrom through the proximal stent section 30 and further proximally out of the coronary sinus 5, through the vein system and out of the human body.

10 In a preferred embodiment schematically illustrated ; in FIG. 15, a second wire 37 extends through the third eyelet 34 and further extends as a double wire proximally from the third eyelet 34, through the proximal stent section 30 and the coronary sinus 5 and then out of the 15 body. The third eyelet 34 will be moved proximally by simultaneous pulling both ends of the second wire 37 outside of the body. When the desired position of the third eyelet 34 is reached, the second wire 37 may easily be removed through the vein system by pulling only one of 20 its ends outside the body.

As illustrated in FIG. 15, a third wire 38 may be extended through the third eyelet 34. Therefrom it extends as a double wire distally to and through the first eyelet 32 and then this double wire extends 25 proximally from the first eyelet 32 (or a further eyelet

20

fixed to the proximal end of the distal stent) through the proximal stent section 30 and finally the double wire 38 extends proximally through the coronary sinus 5 and out of the human body. By pulling both ends of this third wire 38 outside of the body, the third eyelet 34 will allow a movement of the proximal and distal stent sections 30, 31 away from each other. By means of the second wire 37 and the third wire 38 the position of the third eyelet 34 may be adjusted repeatedly until a desired position is attained. The third wire 38 may be removed in the same manner as the second wire 37.

Obviously, the position of the third eyelet 34 may be used to control the distance between the proximal and distal stent sections 30, 31, and this distance controls the radius of curvature of the device and thus also the radius of curvature of the coronary sinus 5.

The further embodiment of the device illustrated in FIG. 16 corresponds to the embodiment illustrated in FIG. 15 except that the first eyelet 32 is fixed to the proximal stent section 30 and the second eyelet 33 is fixed to the distal stent section 31. Therefore, a fourth wire 39 has the same extension as the third wire 38 in FIG. 15 but has the function of the second wire 37 in FIG. 15. A fifth wire 40 has the same extension as the

second wire 37 in FIG. 15 but has the function of the third wire 38 of FIG. 15.

The quotient between the maximum distance and the minimum distance between the proximal stent section 30 and the distal stent section 31 in FIGS 15 and 16 is about 1.5. A quotient of about 2.5 would be possible by letting the wire 35 extend once more via the third eyelet 34 and the first eyelet 32 (or another eyelet fixed at substantially the same position as the first eyelet) before finally extending via the second eyelet 33 back to the third eyelet 34 where the second end of the wire 35 is fixed, as shown in FIG. 17.

According to FIG. 18, the wires 35-40 extending between the proximal stent section 30 and the distal stent section 31 are confined in a plastic sheath or a plastic wire spiral 41 which will cover and protect the wires 35-40. By enclosing the wires 35-40, the sheath or spiral 41 will also prohibit them from cutting through the wall of the coronary sinus 5. Alternatively, more than one sheath or spiral 41 may be used, all of which should be compressible lengthwise so as to allow the reduction of the distance between the proximal and distal stent sections 30, 31.

The embodiments illustrated in FIGS 15-18 may be introduced by conventional means into the coronary sinus

5 via the vein system. Preferably, the distal stent
section 31 first is adjusted to a desired position,
whereupon it is expanded so as to engage the walls of the
coronary sinus 5. Thereby, the position of the distal
5 stent section 31 is fixed in the coronary sinus 5. Then
the position of the proximal stent section 30 is adjusted
considering the required reduction of the distance
between the proximal and distal stent sections 30,
31. Thereafter the proximal stent section 30 is expanded
10 such that it is fixed relative the coronary sinus 5.
Finally, the distance between the proximal and distal
stent sections 30, 31 is reduced using one of the wires
37 and 39. If the distance reduction is found too
extensive, the distance between the stent sections 30 and
15 31 may be increased by pulling one of the wires 38 and
40. After achieving a perfect position, the used wires
37-40 may be removed by pulling in one of the double
ends.

It should be noted that instead of eyelets having a
20 single opening, eyelets having multiple openings could be
used such that each one of the wires extends through an
opening of its own.

Still one further embodiment of the device according
to the present invention is illustrated in FIGS 19 and
25 20. Here, the device comprises an elongate body having

three stent sections, the proximal stent section 30 and the distal stent section 31 being of the same type as described above. A central stent section 42 is such as to reduce its length when expanded radially.

5 When this device is positioned in the coronary sinus 5, the proximal and distal sections 30, 31 are first expanded, as illustrated in FIG. 19, and then the central stent section 42 is expanded. As a consequence of its length reduction when expanded, the central stent section 10 42 will reduce the distance between the proximal and distal stent sections 30, 31 and thus reduce the radius of curvature of the coronary sinus 5, as illustrated in FIG. 20.

Concludingly, the present invention provides a 15 device placed in the coronary sinus 5 and designed to reduce the dilatation of the mitral annulus. This device is at a distance from the attachment of the posterior leaflet that does not much exceed the distance at which present annuloplasty rings are placed by open surgery 20 techniques, and the coronary sinus is along its entire course large enough to hold such a device. The device could be positioned by catheter technique or any other adequate technique and offers a safer alternative to the current open surgery methods. The device could be 25 designed or heparincoated so as to avoid thrombosis in

the coronary sinus, thus reducing the need for aspirin, ticlopedine or anticoagulant therapy.

It is to be understood that modifications of the above-described device and method can be made by people skilled in the art without departing from the spirit and 5 scope of the invention.